ABSTRACT OF PROTOCOL

This protocol is a study of patients with metastatic melanoma who have failed standard therapy. In an attempt to increase the patient's immune response to the tumor, the interleukin-2 (IL-2) gene will be introduced into a human melanoma cell line (M-24). This gene-modified melanoma cell line producing IL-2 will then be mixed with tumor cells obtained from the patient. This mixture of cells will be irradiated to prevent possible growth and injected subcutaneously into the patient. This injection is expected to augment the immune responses of the patient to tumor cells through the immune stimulatory effects of the IL-2 secreted by the gene-modified cells. Animal models have shown the injection of gene modified cells has important antitumor effects. To determine the safety of the procedure, a constant number of tumor cells will be mixed with escalating numbers of IL-2 producing cells.

The patients will be evaluated for antitumor effects engendered by the injection of the gene modified cells mixed with patient tumor cells. The injection of gene modified cells with the tumor cells may serve to "immunize" the patient to their tumor and may be amenable to use in a wide variety of tumor types. This protocol differs from other previous IL-2 "tumor vaccines" in that a wider range of patients and tumor types can potentially be treated as tumor cell lines from each patient do not need to be established.